

REMARKS
---------

***Amendment to the Claims******35 U.S.C. 112, second paragraph rejection***

Claims 1, 3-5, 7-9 and 11 are rejected under 35 U.S.C. 112, second paragraph for use of the phrase "condensation products of polyglycols and amines". Although it is believed that this phrase is clear on its face as the amendment made to claim 1 would appear to obviate this rejection.

***35 U.S.C. 103(a) rejections***

Claims 1, 3, 5, 7-9 and 11 were rejected as being obvious by the examiner over Schreiber et al. (WO 98/17232 - now U.S. patent 6,613,338) in view of Dupuis et al. (U.S. Patent 6,338,858).

Claim 4 was rejected as being obvious by the examiner over Schreiber et al., *id.*, in view of Dupuis et al., *id.*, and further in view of Yoneyama et al. (U.S. Patent 5,015,469).

The core of the applicants position with regard to these rejection remains essentially unchanged. However, in the section below, there is included further exposition as to the points the applicants were trying to make with their previous arguments.

***Addressing Examiner's "Response to Arguments"***

The examiner dismisses the applicants arguments by essentially recopying MPEP 2145 X. A. without further comment. This is objected to for the following reasons:

- (1) MPEP 2144.08 III. states "A determination under 35 U.S.C. 103 should rest on all the evidence and should not be influenced by any earlier conclusion...Thus, once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record." (citations omitted).
- (2) MPEP 2144 includes a section entitled "Legal Precedent Can Provide the Rationale Supporting Obviousness Only if the Facts in the Case Are Sufficiently Similar to Those in the Application". However, there has been no discussion of how the fact pattern in *In re McLaughlin* is similar to the

present application and the prior art cited against the claims.

It has previously been held that "No per se rules of obviousness have been established by precedent, and reliance on any such rules that eliminate the need for fact-specific analysis of claims and prior art is legally incorrect and must cease, since use of per se rules in obviousness determination is inconsistent with 35 U.S.C. § 103, which entitles applicant to issuance of otherwise proper patent unless Patent and Trademark Office establishes that invention, as claimed in application, is obvious over cited prior art, based on specific comparison of that prior art with claim limitations." see *In re Ochiai*, 37 U.S.P.Q. 1128, (Fed. Cir. 1995).

*McLaughlin* dealt with a boxcar invention where the prior art essentially described the claimed invention save for a single element (i.e. there were a limited number of permutations which needed to be considered) which was addressed with a secondary reference and was well known to be used at the time the invention was made. This is not the case in the present application where stepping back to the time the invention was made and without benefit of the applicants' claims as a guideline, there would have been a virtually unlimited number of permutation which could have been made to the prior art.

- (3) The examiner apparently views *In re McLaughlin* as providing a pass from four tenets of patent law which must be adhered to when applying 35 U.S.C. 103 (see MPEP 2144, pg. 2100-116, rev. 1, Feb. 2003). However, this would be incorrect application of *McLaughlin*. The key element from the passage from *McLaughlin* cited by the examiner is "...at time claimed invention was made...".

The ruling on obviousness in *In re Fine* closely adheres to the position maintained by the applicants and is reproduced in part below:

"Obviousness is tested by 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it 'cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.' *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And 'teachings of references can be combined only if there is some suggestion or incentive to do so.' *Id.* Here the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination...

It is essential that 'the decisionmaker forget what he or she has been taught at trial about the claimed invention **and cast the mind back to the time the invention was made...**to occupy the mind of one skilled in the art **who is presented only with the references**, and who is normally guided by the then-accepted wisdom in the art.' *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." see *In re Fine*, 5 USPQ2d 1596, 1599, 1600 (Fed. Cir. 1988).

In *Texas Instruments Inc.* (relying on *Fine*) it was further stated that "[a]bsent such suggestion to combine the references, respondents can do no more than piece the invention together using the patented invention as a template. Such hindsight reasoning is impermissible." see *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1018, 1029 (Fed. Cir. 1993).

Applying these rulings to the present facts at hand, the question becomes:

"As of 9 November 1999 (the filing date of this application), what would have motivated one of ordinary skill in the art to modify the teachings of Schreiber et al. to arrive at the presently claimed invention when not having the luxury of the applicants' claims to provide them with any guidance as to how to modify Schreiber et al.'s teachings?"

Each of the three references relate to composition which have multiple components as required ingredient and expansive descriptions of potential optional components. Even when taken individually, each reference represents an almost infinite number of possible permutations of their invention. When viewed in this light, it is highly unlikely that one of ordinary skill in the art would have magically selected the appropriate elements necessary to match the applicants' invention without using the applicants' claims as a template.

*Rice* is another decision which speaks to the issue of obviousness and reconstruction and offers additional guidance on this point, "...the board said, referring to the appellant's ingredients, 'It should be noted that an infinite number of combinations is possible.' Accepting that as an approximation to the truth, we fail to see the obviousness in devising appellant's particular two-part segregation of ingredients [invention] as claimed." see *In re Rice*, 178 USPQ 478, 480 (CCPA 1973).

Moreover MPEP 2142 states:

"The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness [page 2100-123]...The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it.

With regard to the rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e. the reference teachings establish a *prima facie* case of obviousness) is more probable than not."

Therefore, given that one of ordinary skill in the art would be highly unlikely at the time the invention was made to select the appropriate ingredient out of an infinite number of possibilities available to them, the preponderance of evidence favors the holding that the claims are not obvious in light of the prior art.

### Closing

Applicants also believe that this application is in condition for allowance.<sup>1</sup> However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

<sup>1</sup> It is presumed that the examiner has been made aware of the effects of the *Festo* series of decisions on patent prosecution. If there is an amendment the examiner would like the applicant(s) to make (especially to an independent claim), this must be expressed in the office action as applicant(s) are no longer afforded the luxury of "guessing" what the examiner would find allowable.

As a reminder of the reasons why this is so, selected passages from the recent *en banc* decision by the CAFC on *Festo* (26 September 2003) are provided below:

"...we reinstate those holdings of *Festo VI* that were not disturbed by the Supreme Court. To begin with, we recognize that the Court expressly endorsed our [Federal Circuit's] holding that a *narrowing amendment* made to comply with any provision of the Patent Act, including §112, may invoke an estoppel....When the prosecution history reveals no reason for the narrowing amendment, *Warner-Jenkinson* presumes that the patentee had a substantial reason relating to patentability; consequently, the patentee must show that the reason for the amendment was not one relating to patentability if it is to rebut that presumption....In this regard, we reinstate our earlier holding that a patentee's rebuttal of the *Warner-Jenkinson* presumption is restricted to the evidence in the prosecution record." see *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, No. 95-1086 (Fed. Cir. Sept. 26, 2003), available at <http://www.fedcir.gov/opinions/95-1086e.doc>.

Bayer 10,019.4-HCL

Respectfully submitted,

Norris, McLaughlin & Marcus, P.A.

By: Howard C. Lee  
Howard C. Lee  
Reg. No. 48,104

220 East 42<sup>nd</sup> Street  
30<sup>th</sup> Floor  
New York, New York 10017  
(212) 808-0700

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (9 pages) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 10 October 2003

By: Howard C. Lee  
Howard C. Lee

**RECEIVED  
CENTRAL FAX CENTER**

**OCT 10 2003**

**OFFICIAL**